510(k) Summary

Submitter:	Zimmer Spine 5301 Riata Park Court Austin, TX 78727
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Date:	November 22, 2011
Trade Name:	Trabecular Metal™ Fusion Device
Common Name:	Intervertebral Body Fusion Device
Classification Name and Reference:	Intervertebral Body Fusion Device 21 CFR § 888.3080, ODP

DEVICE DESCRIPTION

The Trabecular Metal™ Fusion Device is an interbody fusion device comprised wholly of porous tantalum Trabecular Metal. The Trabecular Metal™ Fusion Device is implanted in the cervical intervertebral disc space and is intended to facilitate vertebral fusion by stabilizing adjacent vertebrae, maintaining disc height, and preventing the collapsing of one vertebrae onto another.

The Trabecular Metal™ Fusion Device is currently offered in three cross sectional sizes (11x11mm, 11x14mm, and 14x14mm) and in 7° lordotic and 0° non-lordotic configurations. Height options are available in 5, 6, 7, 8, 9, and 10mm sizes. The present 510(k) premarket notification seeks to extend the product line by offering three additional height options of 4, 11 and 12mm sizes to the existing TM-S Fusion Device implant system.

The superior and inferior surfaces of the device have a pattern of ripples and a central hole in the device extending in the superior-inferior direction for placement of bone graft. Additionally, the proposed system contains a central slot on the anterior surface to allow interface with a central inserter.

INDICATIONS FOR USE

The Trabecular Metal™ Fusion Device is a cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with/ without radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Trabecular Metal Fusion Device is intended for use with supplemental fixation systems and with autogenous bone graft. The Trabecular Metal Fusion Device is implanted via an anterior approach.

DEVICE TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE(S)

The Trabecular Metal™ Fusion Device was shown to be substantially equivalent to a legally marketed predicate device. The predicate device selected for use, material, technological characteristics and basic principles of operation was the Zimmer® Trabecular Metal™ Fusion Device (K103033). The predicate device selected for footprint (height) was the Depuy Bengal™ Intervertebral Fusion Device (K081917).

The Trabecular Metal Fusion Device has the identical material as the previously cleared Zimmer Trabecular Metal Fusion Device. The intended use and indications for use of the subject device are identical to that of the Zimmer Trabecular Metal Fusion Device. The sizes of the device in the current submission are identical to the Depuy Bengal Intervertebral Fusion Device.

PERFORMANCE DATA

According to the FDA's "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Intervertebral Body Fusion Device", the following tests are recommended for this type of device: Static Axial Compression, Dynamic Axial Compression, Static Torsion, Dynamic Torsion, Static Compression Shear, Dynamic Compression Shear and Subsidence. Among these tests, subsidence is not affected by the height of an interbody device, given the same cross-section and profile design.

Therefore, mechanical testing was performed on the Trabecular Metal Fusion Device which included Static Axial Compression, Dynamic Axial Compression, Static Torsion, Dynamic Torsion, Static Compression Shear and Dynamic Compression Shear all per ASTM F2077-03. The results of testing and analyses conducted demonstrate that the proposed system is substantially equivalent to the Zimmer Trabecular Metal Fusion Device in terms of mechanical performance.

CONCLUSION

The additional sizes of the Trabecular Metal™ Fusion Device are substantially equivalent to the Zimmer Trabecular Metal Fusion Device with respect to intended use/indications for use, material, technological characteristics and basic principles of operation. As demonstrated by supporting performance data, the introduction of new sizes does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Zimmer Spine, Inc.
% Ms. Jennifer Tribbett
Senior Regulatory Affairs Specialist
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Austin, Texas 78727

Re: K111119
Trade/Device Name: Trabecular Metal™ Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: October 14, 2011
Received: October 17, 2011

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111119

Device Name: Trabecular Metal™ Fusion Device

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111119